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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,530	07/24/2000	Richard Sackler	200.93185C2C	5659

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DAVIDSON, DAVIDSON & KAPPEL, LLC  
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NEW YORK, NY 10018

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/624,530

Applicant(s)

SACKLER ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-10,13-16 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-10,13-16 and 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 6-10, 13-16 and 20-23 are pending. The Amendment filed 10/2/03, Paper No. 21, cancelled claims 11-12 and 17-19.

#### ***Response to Applicant's Arguments/Amendment***

The Applicant's arguments filed 10/2/03 (Paper No. 21) to the rejection of claims 6-10, 13-16 and 20-23 made by the Examiner under 35 USC 102 and 103 have been fully considered and deemed not persuasive.

The Applicant's amendment to the claims is sufficient-in-part to overcome the 35 USC 112 rejection in the previous Office Action. See below for details.

#### ***112 Rejection Maintained***

The rejection of claim 13 is under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed 5/27/03, Paper No. 19, and those found below.

The rejection of the phrase "protein derived materials" is maintained. Applicant argues, that this phrase is an art recognized phrase and provides two patents for evidence. However, Applicant's arguments are not persuasive. The two patents relied upon by Applicant refer to a few specific materials from which proteins can be obtained. However, the patents do not define this phrase and they do not teach what protein derived materials are, they merely teach materials from which proteins can be derived without teaching what protein derived materials are. Thus, this phrase is vague and indefinite.

#### ***102 Rejection Maintained***

The rejection of claims 6-7, 9, 13-16 under 35 U.S.C. 102(e) as being unpatentable over Paradissis et al. (5,133,974) is MAINTAINED for the reasons set forth in the Office Action mailed 5/27/03, Paper No. 19, and those found below.

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Applicant argues, “These coated bead formulations of the Paradissis reference are recognized to one skilled in the art as different than a matrix formulation, as evidenced by the separation discussions of these formulations on page 53 of Pharmacy Review”. This argument is not persuasive. First, the Examiner respectfully points out that Pharmacy Review teaches controlled-release and extended release formulations as synonymous. See A, 1., which states, “Controlled-release dosage forms (also known as. . . extended release forms)”, wherein the instant claims recite controlled release and Paradissis et al. disclose extended release. Second, it is respectfully pointed out that while Paradissis does not explicitly state a matrix, the reference teaches a matrix. The instant claims recite a matrix as comprising a polymer selected from the group consisting of alkyl celluloses and acrylic resins, and Paradissis et al. teach their active ingredient in combination with hydroxypropylmethyl cellulose (alkyl cellulose), hydroxypropyl cellulose (alkyl cellulose), ethylcellulose (alkyl cellulose), acrylic acid copolymers (acrylic acid resin), methacrylic acid copolymers (acrylic acid resin), and mixtures thereof, in their formulation. Thus, while Paradissis does not explicitly state that the drug is in a polymer matrix, the compounds listed above are the same as those making up the matrix of the instant invention.

Applicant argues, “In view of the arguments presented above, it is respectfully submitted that the formulations of the Paradissis reference are different than the formulations recited in the present method claims”. This argument is not persuasive, for the reasons discussed in the previous paragraph.

Applicant argues, “it is respectfully submitted that there is no indication that coated bead opioid analgesic formulations were ever made by Paradissis et al. Therefore, the doctrine of inherency based on Paradissis cannot be relied upon for any claimed based on the present

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specification". This argument is not persuasive. First, the Examiner respectfully points out that there is no indication that the coated bead analgesic formulations were not made. Second, the Examiner respectfully points out that in their claims Paradissis et al. clearly teach coated bead opiod analgesic formulations of the instant claims. Thus, since Paradissis et al. teach the exact same formulations for treating pain as that recited in the instant claims, they must have the exact same properties. Third, the Examiner respectfully points out that even if there is no specific exemplification, Paradissis et al. has enabled one of ordinary skill in the art to make and use their invention.

Applicant argues, "the coated bead formulations of Paradissis are not identical or substantially identical to the coated bead formulations disclosed, but not claimed in the present specification, for example, the Paradissis formulations require a talc coat, which is not contained in the examples of the present application". This argument is not persuasive. The Examiner respectfully points out that Applicant's open-ended language does not exclude additional ingredients from their formulations. Thus, Applicant's arguments are not commensurate in scope with the instant claims.

***103 Rejection Maintained***

The rejection of claims 6-10, 13-16 and 20-23 under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. is MAINTAINED for the reasons set forth in the Office Action mailed 5/27/03, Paper No. 19, and those found below.

Applicant argues, "one skilled in the art would not arrive at the presently claimed invention for the reasons set forth above with respect to the anticipation rejection". This argument is not persuasive. See the above "102 Rejection Maintained" for the Examiner's response to the anticipation argument.

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***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**  
11/3/23